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09/713,545	11/15/2000	Russell N. Van Gelder	LBS-002COB	4526

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EXAMINER

SANDALS, WILLIAM O

ART UNIT	PAPER NUMBER
1636	16

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/713,545	Applicant(s) Van Gelder et al.
	Examiner William Sandals	Art Unit 1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Aug 26, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 43-54 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 43-54 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

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DETAILED ACTION

Response to Amendment

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
3. Claims 43, 45-51, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,112,734 (Kramer et al.) in view of US 5,043,272 (Hartley et al.).

The claims are drawn to a multigene expression profile of a sample comprising linearly amplified specific nucleic acid messages wherein the amplified specific nucleic acid messages have a relative abundance which reflects the relative representation of the specific nucleic acid messages within the sample. The specific nucleic acid messages may comprise cDNA. The specific nucleic acid messages may be hybridized to a target by northern or southern blot. The sample may be a mammalian cell from a tissue source (blood or neural).

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Kramer et al. teach at the summary and columns 5-10, a sample comprising linearly amplified specific nucleic acid messages wherein the amplified specific nucleic acid messages have a relative abundance which reflects the relative representation of the specific nuclei acid messages within the sample. The amplification is produced by using a primer covalently attached to an RNA polymerase promoter to produce a cDNA from an mRNA in a sample wherein the cDNA has the RNA polymerase promoter covalently attached. By adding an RNA polymerase to the cDNA, multiple, linearly amplified RNA copies of the mRNA in the sample may be produced. The specific nuclei acid messages may be hybridized to a target by well known procedures (northern or southern blot). The sample may be a mammalian cell from a tissue source such as blood.

Kramer et al. did not teach a multigene expression profile.

Hartley et al. teach at columns 3-7, and 9-10 a multigene expression profile by amplifying a pool of mRNA's by using a pool of primers which have a covalently attached RNA polymerase promoter, then producing cDNA's from the mRNA's in a sample. The cDNA's have the RNA polymerase promoter covalently attached. By adding an RNA polymerase to the cDNA's, multiple, linearly amplified RNA copies of the mRNA's in the sample may be produced. The specific nuclei acid messages may be hybridized to a target by well known procedures (northern or southern blot). The sample may be a mammalian cell from a tissue source.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of Kramer et al. and Hartley et al. to produce the

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instant invention. Kramer et al. and Hartley et al. each made obvious the instant claimed invention because they both teach a sample comprising linearly amplified specific nucleic acid messages wherein the amplified specific nucleic acid messages have a relative abundance which reflects the relative representation of the specific nucleic acid messages within the sample. The specific nucleic acid messages may comprise cDNA. The specific nuclei acid messages may be hybridized to a target by northern or southern blot. The sample may be a mammalian cell from a tissue source. Hartley et al. provide additional teachings showing that the linearly amplified specific nucleic acid messages may be from a pool of messages (a multigene expression profile of a sample).

One of ordinary skill in the art would have been motivated to combine the teachings of Kramer et al. and Hartley et al. to produce the instant invention because each of Kramer et al. and Hartley et al. teach the desirable and beneficial use of a sample comprising linearly amplified specific nucleic acid messages and Hartley et al. teach the amplification of a pool of a sample (a multigene expression profile of a sample) comprising linearly amplified specific nucleic acid messages for the desirable benefit of screening many messages in a single rapid procedure. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Kramer et al. and Hartley et al.

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4. Claims 43-51, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al. and Hartley et al. as applied to claims 43, 45-51, 53 and 54 above, and further in view of US 5,466,788 (Ahlquist et al.).

The claims are drawn to the invention described above and where the message is aRNA.

Kramer et al. and Hartley et al. teach the invention as described above.

Kramer et al. and Hartley et al. do not teach that the message is aRNA.

Ahlquist et al. teach at column 4-5 and 9, the production of linearly amplified specific messages by adding an RNA promoter onto a nucleic acid sequence, adding RNA polymerase and producing linearly amplified specific messages. Ahlquist et al. teach the advantages of producing aRNA for producing an alternate form of nucleic acid which is useful for producing the linearly amplified specific nucleic acid messages.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of Kramer et al. and Hartley et al. with Ahlquist et al. to produce the instant invention. Kramer et al., Hartley et al. and Ahlquist et al. each made obvious the instant claimed invention because they teach a sample comprising linearly amplified specific nucleic acid messages wherein the amplified specific nucleic acid messages have a relative abundance which reflects the relative representation of the specific nucleic acid messages within the sample. The specific nucleic acid messages may comprise cDNA. Ahlquist et al. provide additional teachings showing that the linearly amplified specific nucleic acid messages may be from aRNA messages.

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One of ordinary skill in the art would have been motivated to combine the teachings of Kramer et al. and Hartley et al. with Ahlquist et al. to produce the instant invention because each of Kramer et al. and Hartley et al. with Ahlquist et al. teach the desirable and beneficial use of a sample comprising linearly amplified specific nucleic acid messages and Ahlquist et al. teach the desirable benefit of using aRNA for producing an alternate form of nucleic acid which is useful for producing the linearly amplified specific nucleic acid messages. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Kramer et al., Hartley et al. and Ahlquist et al.

5. Claims 43-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al., Hartley et al. and Ahlquist et al. as applied to claims 43-51, 53 and 54 above, and further in view of Kwoh et al.

The claims are drawn to the invention described above and where the sample is a single cell.

Kramer et al., Hartley et al. and Ahlquist et al. teach the invention as described above.

Kramer et al., Hartley et al. and Ahlquist et al. do not teach that the sample is a single cell.

Kwoh et al. teach at the abstract, linearly amplified specific messages produced by adding an RNA promoter onto a nucleic acid sequence, adding RNA polymerase and producing

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linearly amplified specific messages, where the linearly amplified specific messages are from a single cell which has been previously unattainable.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of Kramer et al., Hartley et al. and Ahlquist et al. with Kwoh et al. to produce the instant invention. Kramer et al., Hartley et al. and Ahlquist et al. with Kwoh et al. each made obvious the instant claimed invention because they teach a sample comprising linearly amplified specific nucleic acid messages wherein the amplified specific nucleic acid messages have a relative abundance which reflects the relative representation of the specific nucleic acid messages within the sample. The specific nucleic acid messages may comprise cDNA. Kwoh et al. provide additional teachings showing that the linearly amplified specific nucleic acid messages may be from single cell.

One of ordinary skill in the art would have been motivated to combine the teachings of Kramer et al., Hartley et al. and Ahlquist et al. with Kwoh et al. to produce the instant invention because each of Kramer et al., Hartley et al., Ahlquist et al. and Kwoh et al. teach the desirable and beneficial use a sample comprising linearly amplified specific nucleic acid messages wherein the amplified specific nucleic acid messages have a relative abundance which reflects the relative representation of the specific nucleic acid messages within the sample and Kwoh et al. teach the desirable benefit that the amplification may be done on a sample which comprises a single cell which has been previously unattainable. Further, a person of ordinary skill in the art would have

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had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Kramer et al., Hartley et al. and Ahlquist et al. with Kwoh et al.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Certain papers related to this application are **welcomed** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If

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applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the William Phillips, whose telephone number is (703) 305-3482.

William Sandals, Ph.D.

Examiner

November 17, 2002



TERRY MCKELVEY
PRIMARY EXAMINER